

In the Claims

1-86. (Cancelled)

87. (Currently Amended) A process for preparing a lipid suspension, the method comprising:

(a) contacting at least two individual, purified, phospholipids [[lipids]] with a first non-aqueous solvent which causes the phospholipids [[lipids]] to dissolve and form a lipid solution, wherein the contacting comprises the sequential addition of the at least two phospholipids to the first non-aqueous solvent, or combining the at least two individual phospholipids with each other prior to their addition to the first non-aqueous solvent;

(b) contacting the lipid solution with a second non-aqueous solvent which causes the lipids to precipitate out as a solid lipid blend;

(c) collecting the solid lipid blend;

(d) contacting the solid lipid blend with a third non-aqueous solvent which causes the lipid blend to dissolve to form a lipid blend solution;

(e) contacting the lipid blend solution with an aqueous solution to yield a lipid suspension.

88. (Previously Presented) The process of Claim 87, wherein each of the lipids has a gel to liquid crystalline phase temperature and wherein the lipid blend solution of step (d) is heated to a temperature that is about equal to or above the highest gel to liquid crystalline phase temperature of the lipids.

89. (Previously Presented) The process of Claim 87, wherein the first non-aqueous solvent is a mixture of methanol and toluene.

90. (Previously Presented) The process of Claim 87, wherein the second non-aqueous solvent is methyl *t*-butyl ether.

91. (Previously Presented) The process of Claim 87, wherein the third non-aqueous solvent is selected from propylene glycol, ethylene glycol, and polyethylene glycol 300.

92. (Previously Presented) The process of Claim 91, wherein the third non-aqueous solvent is propylene glycol.

93. (Previously Presented) The process of Claim 87, wherein the aqueous solution is water, saline, a saline and glycerin mixture, or a saline and glycerin and non-aqueous solvent mixture.

94. (Previously Presented) The process of Claim 93, wherein the aqueous solution is a saline and glycerin mixture.

95. (Previously Presented) The process of Claim 93, wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

96. (Previously Presented) The process of Claim 87, wherein the first non-aqueous solvent is a mixture of methanol and toluene and wherein the second non-aqueous solvent is methyl *t*-butyl ether.

97. (Previously Presented) The process of Claim 87, wherein the third non-aqueous solvent is propylene glycol and wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

98. (Previously Presented) The process of Claim 96, wherein the third non-aqueous solvent is propylene glycol and wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

99. (Previously Presented) The process according to Claim 98, wherein sodium chloride glycerin propylene glycol and about 0.75 to 1.0 mg/mL of the lipid blend are present in the lipid suspension.

100. (Previously Presented) The process according to Claim 87, wherein the third non-aqueous solvent is heated to a temperature of about 30 to 70°C prior to contacting with the solid lipid blend.

101. (Previously Presented) The process according to Claim 87, wherein the third non-aqueous solvent is heated to a temperature of about 50 to 55°C prior to contacting with the solid lipid blend.

102. (Previously Presented) The process according to Claim 87, wherein in step (d) the ratio of solid lipid blend to third non-aqueous solvent is from about 5 mg of solid lipid blend per mL of non-aqueous solvent to about 15 mg/mL of solid lipid blend per mL of non-aqueous solvent.

103. (Previously Presented) The process according to Claim 102, wherein the ratio of solid lipid blend to third non-aqueous solvent is about 10 mg/mL.

104. (Previously Presented) The process according to Claim 87, wherein in step (e), the aqueous solution is heated to a temperature of about 45 to 60°C prior to contacting with the lipid blend solution.

105. (Previously Presented) The process according to Claim 104, wherein the aqueous solution is heated to a temperature of about 50 to 55°C prior to contacting with the lipid blend solution.

106. (Previously Presented) The process according to Claim 89, wherein the lipid blend solution is heated to a temperature of at least about 67°C.

107. (Previously Presented) The process according to Claim 89, wherein step (d) of the process further comprises:

filtering the lipid blend solution through a sterilizing filter to form a filtered lipid blend solution.

108. (Previously Presented) The process according to Claim 107, wherein step (d) of the process further comprises:

filtering the filtered lipid blend solution through a second sterilizing filter to form a twice filtered lipid blend solution.

109. (Previously Presented) The process according to Claim 108, wherein the sterilizing filters are at a temperature of from about 70 to 80°C.

110. (Previously Presented) The process according to Claim 109, wherein 0.2 μ m hydrophilic filters are used.

111. (Previously Presented) The process according to Claim 107, wherein the process further comprises:

dispensing the filtered lipid blend solution into a vial.

112. (Previously Presented) The process according to Claim 111, wherein the process further comprises:

exchanging the headspace gas of the vial with a perfluorocarbon gas.

113. (Previously Presented) The process according to Claim 112, wherein the perfluorocarbon gas is perfluoropropane.

114. (Previously Presented) The process according to Claim 113, wherein exchange of headspace gas is performed using a lyophilizing chamber.

115. (Previously Presented) The process according to Claim 112, wherein the process further comprises: sterilizing the vial.

116. (Previously Presented) The process according to Claim 115, wherein the vial is sterilized at about 126-130°C for 1 to 10 minutes.

117. (Previously Presented) The process of Claim 87, 88, 96, 97, 100, 102 or 104 wherein the lipids comprise:

- (a) 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine;
- (b) 1,2-dipalmitoyl-*sn*-glycero-3-phosphotidic acid, mono sodium salt; and,
- (c) *N*-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine, mono sodium salt.

118. (New) The process of Claim 87, wherein

(i) the purified phospholipids comprise:

- (i') 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine;
 - (i'') 1,2-dipalmitoyl-*sn*-glycero-3-phosphotidic acid, mono sodium salt; and,
 - (i''') *N*-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine, mono sodium salt;
- (ii) the first non-aqueous solvent is a mixture of methanol and toluene;
- (iii) the second non-aqueous solvent is methyl *t*-butyl ether;
- (iv) the third non-aqueous solvent is propylene glycol;
- (v) the aqueous solution is water, saline, a saline and glycerin mixture, or a saline and glycerin and non-aqueous solvent mixture;
- (vi) the third non-aqueous solvent is heated to a temperature of about 30 to 70°C prior to contacting with the solid lipid blend;
- (vii) in step (d) the ratio of solid lipid blend to third non-aqueous solvent is from about 5 mg of solid lipid blend per mL of non-aqueous solvent to about 15 mg/mL of solid lipid blend per mL of non-aqueous solvent;

- (viii) in step (e), the aqueous solution is heated to a temperature of about 45 to 60°C prior to contacting with the lipid blend solution;
- (ix) step (d) of the process optionally comprises filtering the lipid blend solution through a sterilizing filter to form a filtered lipid blend solution;
- (x) the process comprises dispensing the filtered lipid blend solution into a vial;
- (xi) wherein the process comprises exchanging the headspace gas of the vial with perfluoropropane; and
- (xii) the process comprises sterilizing the vial.

119 (New) The process according to Claim 118, wherein sodium chloride glycerin propylene glycol and about 0.75 to 1.0 mg/mL of the lipid blend are present in the lipid suspension.